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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,144

08/04/2003

Jin Lee

TRA-006.01

5095

25181

7590

07/27/2007

FOLEY HOAG, LLP  
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/634,144	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Gollamudi S. Kishore, Ph.D	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-10 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 11-28 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group II in the reply filed on 2-9-07 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner. This is not found persuasive because the examiner is required to show one-way distinctiveness between the product claims and the process claims and the examiner has done so. Furthermore, the process claims are classified in class 264 which is different from the class the product belongs to which established the burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 11-28 and 32.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11, 13-15, 17-18, 20, 22, 24-28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Abra (6,126,966).

Abra discloses a method of preparation of liposomes containing cisplatin. The method involves dissolving cisplatin in sodium chloride solution and mixing the solution with a lipid mixture at 60-65 degrees. The liposomes were then extruded through filters and the temperature of the liposomes at this state is 20-30 degrees (Example 3).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12, 16, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abra cited above, in view of Ye et al (5,997,899).

The teachings of Abra have been discussed above. What is lacking in Abra is the repetition of the heating and cooling. Abra does not teach the use of DPPC for the formation of liposomes

Ye et al while disclosing a method of preparation of liposomes teach that three cooling and heating cycles across the phase transition temperature facilitates drug equilibrium across the bilayer membranes. One of the phospholipids taught is DPPC (Example 5).

To employ three cooling and heating cycles in the method of preparation of liposomes of Abra would have been obvious to one of ordinary skill in the art since Ye et al teach that three cooling and heating cycles across the phase transition temperature facilitates drug equilibrium across the bilayer membranes. The use of DPPC instead of HSPC taught by Abra would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since it is a commonly used phospholipid in the preparation of liposomes as shown by Ye et al.

6. Claims 11-28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi (US2002/0182248) in combination with Abra and Ye et al both cited above.

Yamauchi teaches a method of encapsulating a drug in liposomes by mixing the lipids with an aqueous solution of a drug, heating it above the transition temperature of the membrane and then cooling it. The preparation is extruded through a membrane filter (0043, 0051 and 0057). What is lacking in Yamauchi is the use of cisplatin as the drug and also repeating the steps of changing the temperature in two or more cycles.

Abra as pointed out above, discloses a method of preparation of liposomes containing cisplatin. The method involves dissolving cisplatin in sodium chloride solution and mixing the solution with a lipid mixture at 60 to 65 degrees. The liposomes were then extruded through filters and the temperature of the liposomes at this state is 20-30 degrees (Example 3).

Ye et al as pointed out above, while disclosing a method of preparation of liposomes teach that three cooling and heating cycles across the phase transition temperature facilitates drug equilibrium across the bilayer membranes. One of the phospholipids taught is DPPC (Example 5).

The use of a platinum drug such as cisplatin in the method of Yamauchi would have been obvious to one of ordinary skill in the art since Yamauchi teaches that any drug can be encapsulated and the reference of Abra shows the knowledge in the art of encapsulating cisplatin. To employ three cooling and heating cycles in the method of preparation of liposomes of Yamauchi would have been obvious to one of ordinary skill

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in the art since Ye et al teach that three cooling and heating cycles across the phase transition temperature facilitates drug equilibrium across the bilayer membranes. The use of DPPC would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since it is a commonly used phospholipid in the preparation of liposomes as shown by Ye et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK